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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,657	12/22/2004	Cinderella Christina Gerhardt	F7649(V)	9203

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

MAIL DATE	DELIVERY MODE
10/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,657	GERHARDT ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-9 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-9 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20051212*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The disclosure is objected to because of the following informalities: Either the heading "Brief Description of the Drawings" should be inserted at page 27, between lines 8 and 9, or else an entire section including the heading "Brief Description of the Drawings" should be inserted, e.g., at page 10, after line 20. See 37 CFR 1.74. Appropriate correction is required.

2. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 is dependent upon canceled claim 10.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5, 7-9, and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 15 of copending Application No. 10/539,434. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '434 application anticipate instant claims 1, 3, 5, 7-9, and 12. Because the same active agent is being administered to the same

subject according to the same method steps, inherently obesity and/or being overweight will be prevented in the claimed method of the '434 application to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the claimed method of the '434 application and the instant claimed method to shift the burden to Applicants to provide evidence that their claimed method is unobviously different than the claimed method of the '434 application. Further, the '434 application claims its method as part of a dietary plan or a weight management program (see claim 7 of the '434 application). With respect to instant claim 4, while the '434 application claims the use of a mixture of hydrolysates of β-lactoglobulin and α-lactalbumin, the '434 application does not claim a weight ratio for these two components. It would have been obvious to one of ordinary skill in the art to determine all operable and optimal component ratios for the hydrolysates of β-lactoglobulin and α-lactalbumin administered in the claimed method of the '434 application, because component ratio is an art-recognized result-effective variable which is routinely determined and optimized in the food and drug arts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Portman (U.S. Patent No. 6,207,638). Portman teaches a nutritional composition which enhances and extends satiety and which stimulates the release of cholecystokinin. The compositions are used to cause weight loss. The nutritional composition comprises whey protein. The compositions can be in the form of a dry powder which can be mixed with a drink, and can form part of a soup or a cereal or a candy bar. See, e.g., the abstract; column 6, line 65 - column 7, line 53; column

9, lines 21-40; column 10, lines 21-23; and claim 1. Note that Applicants' claims have been amended to embrace administration of whey protein as an alternative to whey protein hydrolysate. In view of the similarity in chemical composition, cholecystokinin-releasing function, and method of use between the compositions of Portman and the compositions recited in Applicants' claims, inherently administration of the compositions of Portman will result in induced cellular release of glucagon-like peptides to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of Portman and Applicants' claimed method to shift the burden to Applicants to provide evidence that Applicants' claimed method is unobviously different than the method of Portman. Note that a prior art reference need not recognize or suggest Applicants' intended results in order to anticipate Applicants' claimed methods on the basis of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1391 (BPAI 1993). See also In re Cruciferous Sprouts Litigation, 64 USPQ2d 1202 (Fed. Cir. 2002) and MPEP 2112 and 2112.01.

6. Claims 1, 3-5, 8, 9, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Davis et al (U.S. Patent No. 6,630,320). Davis et al teach orally administering to mammals a composition comprising hydrolyzed whey proteins. The composition comprises whey proteins, including β-lactoglobulin and α-lactalbumin in ratios embraced within the range recited in instant claim 4, subjected to hydrolysis with trypsin to a degree of hydrolysis ranging from 4.5% to 17%. The compositions in powder form can be dissolved in PBS for oral administration. See, e.g., the Abstract; column 2, lines 15-17 and 25-37; column 5, lines 51-55; column 8, lines 9-19; and claims 1 and 3-5. In view of the similarity in chemical composition, method of making the chemical composition, and method of administering the chemical composition, between Davis et

al and Applicants' claims, inherently administration of the compositions of Davis et al will result in induced cellular release of glucagon-like peptides and cholecystokinins and will result in prevention of obesity or being overweight to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of Davis et al and Applicants' claimed method to shift the burden to Applicants to provide evidence that Applicants' claimed method is unobviously different than the method of Davis et al. Note that a prior art reference need not recognize or suggest Applicants' intended results in order to anticipate Applicants' claimed methods on the basis of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1391 (BPAI 1993). See also In re Cruciferous Sprouts Litigation, 64 USPQ2d 1202 (Fed. Cir. 2002) and MPEP 2112 and 2112.01.

7. Claims 1, 3-5, 7-9, and 12 are rejected under 35 U.S.C. 103(a) as being obvious over Davis et al (U.S. Patent No. 6,630,320) as applied against claims 1, 3-5, 8, 9, and 12 above, and further in view of Katz et al (U.S. Patent Application Publication 2002/0081315) and Ward et al (U.S. Patent Application Publication 2003/0165574). Davis et al teach treating patients with hypertension using hydrolyzed whey protein designated hydrolysate 601, which acts as an ACE inhibitor (see, e.g., the Abstract; column 4, lines 46-50; and column 9, lines 50-53), but do not teach treating hypertensive subjects who are also obese or overweight. Katz et al teach that being overweight or obese are known risk factors for hypertension. See paragraph [0008]. Ward et al teach that whey proteins which are capable of inhibiting ACE are useful in enhancing weight loss. See paragraph [0026], and note that this disclosure of Ward et al is also found in provisional application 60/360,709 (see page 9, paragraph [24]) of which Ward et al claim the benefit under 35 U.S.C. 119(e). It would have been obvious to one of ordinary skill in the art at

the time Applicants' invention was made to treat hypertensive patients who are also obese according to the method of Davis et al, because Katz et al teach that obesity and hypertension are commonly associated with each other, and because Ward et al teach that the treatment of Davis et al, due to ACE inhibition, would have been expected to have the additional benefit of enhancing weight loss in the patients being treated.

8. Applicant's arguments filed August 13, 2007 have been fully considered but they are not persuasive.

The prior art rejections set forth in the Office action mailed April 11, 2007 are withdrawn in favor of the references applied above, which are deemed closer in subject matter to that of the amended claims. It should be noted that the amended claims, to the extent that they embrace "preventing" obesity or being overweight, do not require administering to a subject who is actually obese or overweight. Further, as stated in the first Office action and repeated above, where there is sufficient evidence that Applicants' claimed results may be inherent in the prior art, the prior art is not distinguished merely on the basis that it does not recite or even suggest such inherent results.

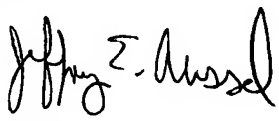
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

September 27, 2007